Ms. Monet Vela
Office of Environmental Health Hazard Assessment
P.O. Box 4010, MS 23 11F
Sacramento, CA 95812-4010
monet.vela@oehha.ca.gov
P65Public.Comments@oehha.ca.gov

Re: Calculating Exposure - Arithmetic Mean, Facility-Based Averaging and Producer-Based Averaging.

The food industry organizations listed below (hereinafter "Food Coalition") thank you for the opportunity to submit comments regarding the Office of Environmental Health Hazard Assessment's (OEHHA) October 2018 proposal to require the use of the arithmetic mean in all circumstances to calculate the "reasonably anticipated rate of intake or exposure" for Proposition 65 compliance evaluations and to require facility-by-facility and producer-by-producer averaging (the "Mandated Calculation Proposal" or "Proposal"). Our coalition consists of the Agricultural Council of California, the American Beverage Association, the California League of Food Producers and the Grocery Manufacturers Association. Each Food Coalition member also has joined in the California Chamber of Commerce comments; we write separately to emphasize how concerning and burdensome this proposal is for the food industry.

I. Overview

Proposition 65 has been a significant burden on the food industry. Moreover, the implementation of Proposition 65 has placed the food industry as the punching bag in disagreements over science and public health communication between the State of California on the one hand and leading expert food safety authorities on the other hand. Litigation concerning fruit juice and coffee are just two examples of the tremendous multi-million dollar burdens on the food industry that Proposition 65 is imposing, with no public health benefit. Moreover, private enforcement of Proposition 65 is increasingly targeting the food industry. In 2008, there were approximately 106 food companies targeted in Proposition 65 notices. In 2017, that number had risen to approximately 1138 food companies targeted in notices.

Against the weight of this significant burden, OEHHA should not adopt proposals that would remove scientifically sound and settled Proposition 65 compliance approaches for this unique, burden-shifting law. No other California or Federal law so dramatically and expensively shifts the burden of proof from the plaintiff to the defendant. No other California or Federal law so conservatively calls for "known to cause" reproductive toxicity warnings when the exposure at issue is 500, 800 or 900 times below a conservatively established no observable effect level.

Although California has expressed concerns about "over warning" under Proposition 65, these proposals could well increase questionable warnings on food products.

OEHHA's proposal to mandate the arithmetic mean rather than allow courts to apply the best science to a particular set of facts should be withdrawn. Likewise, its exorbitantly expensive and unworkable proposal to mandate facility-by-facility or producer-by-producer compliance assessments in all circumstances should be withdrawn.

II. OEHHA Should Not Mandate Using the Arithmetic Mean

OEHHA first proposed the concept of a mandatory one-size-fits-all arithmetic mean in an August 28, 2015 pre-regulatory proposal. The Food Coalition and others opposed this mandatory arithmetic mean proposal as not consistent with the best science.

The Food Coalition strongly opposes the Mandated Calculation Proposal and requests that OEHHA eliminate it from further consideration. Mandatory use of the arithmetic mean would mark a new policy for OEHHA, not a clarification of an existing policy. Mandating the arithmetic mean is inconsistent with sound principles of statistics and science, guidance from the U.S. Centers for Disease Control and Prevention ("CDC"), and the preceding 30 years of Proposition 65 implementation. It would have a significant adverse economic impact on business, including small business. And finally, it likely would increase the number of warnings provided to consumers without a sound legal, policy, or scientific basis. The Proposal should not be adopted.[1]

For 30 years, the Proposition 65 regulations have required compliance to be measured based on "the reasonably anticipated rate of intake or exposure for average users of the consumer product" at issue. 27 C.C.R. § 25821(c)(2). The term "average" acknowledges that different consumers use the same product in varying amounts and with varying frequencies, and that *all* consumers, not some, would receive any warning. For example, if a Proposition 65 warning were required based on exposures to the relatively few consumers who ingest a food product in unusually large quantities and very frequently, there would be unnecessary and misleading warnings provided for the majority of consumers who consume the food product in smaller quantities and less frequently. Consequently, the regulations appropriately refer to the exposure level of "average" users.

There are various methods to determine the reasonably anticipated rate of intake or exposure for average users, and courts have applied the term "average" on a case-by-case basis to different

[1] During a meeting to discuss the Proposal, OEHHA staff observed that OEHHA was not proposing to change the prefatory language of subsection 25821(c) to the effect that the "assumptions" enumerated in subsection (c) need not be used when "more specific and scientifically appropriate data are available." OEHHA advised that, therefore, it was not the Agency's intent to eliminate use of the geometric mean when it is more scientifically appropriate to do so. We have concerns that this intent is not accurately reflected in OEHHA's Proposal or the ISOR. If it is OEHHA's intent to permit the use of the geometric mean when it is more scientifically appropriate, OEHHA should keep the *status quo*.

patterns of consumption and exposure, based on expert testimony and other evidence. Indeed, the Mandated Calculation Proposal directly contradicts the Court's finding in *Environmental Law Foundation v. Beech-Nut Nutrition Corp.*, 235 Cal. App. 4th 307 (2015) ("Beech-Nut"). In that case, after taking expert testimony and considering other evidence, the Superior Court determined that the use of the geometric mean was more appropriate than the arithmetic mean in calculating "the reasonably anticipated rate of intake or exposure by average users" of the food products at issue; the Court of Appeal upheld this conclusion. Indeed, the trial court noted that even the plaintiff's expert in that case used the geometric mean for skewed data in that expert's peer-reviewed publications. *Environmental Law Foundation v. Beech-Nut Nutrition Corp.*, 2013 WL 5402373, *14 (July 31, 2013). In light of this history, it is not credible for OEHHA to contend that the application of the geometric mean to skewed data is a mistake, or is not scientifically sound.

A. The Arithmetic Mean is not "The Appropriate Approach" in Many Cases

The Mandated Calculation Proposal is based on an unsubstantiated and incorrect assertion that the arithmetic mean is "the appropriate approach" to identify the average in all situations:

> "Clarifying that the arithmetic mean of the intake of exposure level for users of a consumer product is the appropriate approach helps the responsible business to correctly determine the rate of intake or exposure for average users of the consumer product and to decide whether a warning is required for a given exposure to a reproductive toxicant." (Initial Statement of Reasons, Proposed Amendment to Title 27, California Code of Regulations, Sections 25821(a) and (c), October 2018 (hereinafter "ISOR") at 4.)

As scientific experts from Exponent and Dr. Jay Murray note in the attached letters analyzing the Proposal, mandating averaging through the arithmetic mean is not always the most scientifically appropriate approach. The Food Coalition urges that OEHHA preserve the *status quo* so that the most appropriate measure of the average consumer's exposure, one supported by scientific principles, may be identified in each case.

OEHHA's explanation for the proposed mandated arithmetic mean is found on pages 6 to 9 of the Initial Statement of Reasons. These explanations are described and assessed below.

OEHHA's first justification for mandating the arithmetic mean appears at the top of page 7 of the ISOR:

> "This proposed amendment identifies the arithmetic mean of measured intake rates or exposures as the method for identifying an average value, regardless of the shape of the distribution that best describes the sampling data.[ ] This is because the arithmetic mean takes into account the magnitudes of all measured values and is an estimate of the expected (i.e., average) magnitude of intake or exposure." (ISOR at 7).

This asserted justification for mandating the arithmetic mean is not really a justification at all. Here, OEHHA notes that the arithmetic mean accounts for the magnitudes of all measured values; however, it does not state that the arithmetic mean is the *best* method to account for the magnitudes of all measured values, because it is not when the data are skewed. Likewise, this justification does not say that the arithmetic mean is scientifically more appropriate than the geometric mean, because it is not when the data are skewed. Indeed, this justification for mandating the arithmetic mean merely boils down to an assertion that the arithmetic mean is one way to identify an average; it does not describe it as superior to or in any way preferred over the geometric mean, and it is not.

OEHHA's second justification for mandating the arithmetic mean is simply an assertion (without support, analysis or rationale) that the "familiar" arithmetic mean is "the appropriate metric." (ISOR at 7). This simple assertion does not support regulatory action.

OEHHA's third justification for mandating the arithmetic mean is that doing so will add "clarity and consistency to the exposure calculation." (ISOR at 7). There is nothing unclear or inconsistent with utilizing the most appropriate statistical method to analyze a particular data set, which is what happens now. OEHHA has not identified any current problem with clarity or consistency in the current or historical implementation of Proposition 65. OEHHA's unsupported assertion, by implication, that the *status quo* needs more clarity or consistency is incorrect.

OEHHA's fourth justification for mandating the arithmetic mean is that "the geometric mean is not typically used for identifying average consumption or usage levels of a food or consumer product." (ISOR at 8). This assertion is made without citation or support, and is baseless, as evidenced by the CDC guidance that the California Chamber and others described to OEHHA in November 2015. It is particularly disappointing that OEHHA is making this assertion while failing to address obviously contrary facts that have been previously submitted to it on this very issue. The attached Exponent analysis further elaborates on this point.

OEHHA's fifth justification for mandating the arithmetic mean is that "the more variable the measurements, the more the geometric mean underestimates the expected exposure." (ISOR at 8). This justification is tautological and assumes, without demonstrating, that the arithmetic mean always is the more appropriate measurement of the average, which is not the case. As Exponent and Dr. Murray explain in the attached, use of the arithmetic mean overstates the scientifically most appropriate measurement of the average for skewed data.

OEHHA next asserts that the median (*i.e.*, the 50^{th} percentile) is not appropriate as a measurement of the average because it "does not take into account exposures of those people who consume more or less of a food or product than typical consumers . . . because the median falls at the midpoint of the distribution where 50 percent of individuals surveyed have higher levels of consumption of a particular food or product and 50 percent have lower levels of consumption, without regard to actual consumption levels above or below the midpoint." (ISOR

at 8). It is not accurate to assert that the median does not "take into account" other values. The median assures that when a Proposition 65 warning is provided, the warning is appropriate for approximately half of the relevant consumers. To mandate the arithmetic mean for a skewed data set, as opposed to the median, would mean that the warning overstates (or understates) the actual level of concern for over half of the relevant consumers. When the data set is skewed to the right, this is a form of over warning that OEHHA and the Administration have noted is a concern for Proposition 65 implementation. The Food Coalition therefore disagrees with OEHHA's assertion that "the median does not provide a measure of expected consumption levels for a food or consumer product except where the distribution is symmetrical." (ISOR at 8). The median always provides a measure of expected consumption or exposure levels; to say otherwise is nonsensical. Rather, it is the arithmetic mean that does not provide a measure of expected consumption levels for a food or consumer product except where the distribution is symmetrical.

OEHHA's seventh justification for mandating the arithmetic mean is that it "weigh[s] the intake of each consumer equally." (ISOR at 8). OEHHA asserts that this equal weighing is somehow appropriate in light of the intent for Proposition 65 to "warn Californians of significant exposures to listed chemicals." (ISOR at 8). Yet, if OEHHA mandates the arithmetic mean always be used, the number of warnings will increase for exposures that are not significant, because the level at which a warning would be required would be one where, with a skewed data set, a strong majority of warning recipients would have exposures below the level requiring a warning, as Dr. Murray and Exponent explain.

OEHHA's eighth explanation for the Proposal asserts that "Clarifying that the arithmetic mean of the intake or exposure level for users of a consumer product is the appropriate approach will help businesses to determine the correct rate of intake or exposure for average users of the consumer product so they can decide whether a warning is required under Proposition 65." (ISOR at 9). The Food Coalition strongly disagrees with the proposition that businesses will be "helped" by this proposed regulation. To the contrary, many businesses will need to revise existing compliance assessments that currently, and appropriately, utilize the geometric mean for skewed data. This will be an added, unnecessary and unwarranted cost that will hurt, not help, businesses with no added consumer benefit.

Finally, the Mandated Calculation Proposal theorizes that the arithmetic mean is appropriate "[b]ecause Proposition 65 is intended to warn Californians of significant exposures to listed chemicals," and therefore, "a determination of the exposures to a chemical in a food or consumer product should be based on the full range of exposures experienced by Californians." (ISOR at 8). This rationale is unfounded since both the arithmetic mean and the geometric mean take into account the full range of exposures experienced by Californians. The difference is the geometric mean provides an average value that is closer to the typical consumer than the arithmetic mean when the data are skewed to the right, which is often the case with exposures to food. The Proposal states: "It is appropriate to weigh all individuals equally for purposes of calculating intakes or exposures." (*Id.*) But, this statement ignores the fact that, for a skewed data set, a

relatively small number of data points can have a disproportionate impact on the arithmetic mean to the point where the average no longer is representative of the typical individual. In other words, using the arithmetic mean for skewed exposure data results in warnings being driven by atypical consumers, not by average consumers.

Further, it is important to recognize that Proposition 65 reproductive toxicity warnings are provided for exposures well *below* the no observable effect level, by statute. Cal. Health & Safety Code § 25249.10(c). By definition, a Proposition 65 maximum allowable dose level ("MADL") provides a high degree of protection since it represents a level of exposure which is 1000-times less than the No Observable Effect Level ("NOEL") in the most sensitive study of sufficient quality. 27 C.C.R. §§ 25801-25821. So, for the consumers below the average, their exposure is more than 1000-fold below the conservatively-defined NOEL. Allowing a minority of consumers at the high end of the distribution curve to have a disproportionate impact on the average will result in needless warnings and subvert the overall regulatory focus on warnings targeting average, not atypical, consumers.

Over warning is not a public benefit under Proposition 65. It is likely that the Health and Welfare Agency, OEHHA's predecessor, had this in mind when it wrote that warnings should be based on "the reasonably anticipated rate of intake or exposure for average users of the consumer product."

B. The Mandated Calculation Proposal is a New Proposed Policy, Not a Clarification of an Existing Policy

Although OEHHA repeatedly states that the Mandated Calculation Proposal is meant to "clarify" Section 25821(c), and thereby implies that the categorical use of the arithmetic mean has been OEHHA's long-held position, this is not the case. OEHHA cites to no statement prior to the beginnings of this proposal in August of 2015 that only the arithmetic mean can be used to calculate exposure and intake levels for reproductive toxicants. Indeed, we have yet to identify a single statement by OEHHA to the effect that OEHHA's position has been that the arithmetic mean must be used under Section 25821.

C. The Proposal Contradicts Specific Guidance from the CDC

OEHHA's proposal to require the use of the arithmetic mean in calculating exposure is not supported by OEHHA's own actions and practices – or those of other agencies that conduct risk assessments. The Proposal states: "However, the geometric mean is not typically used for identifying average consumption or usage levels of a food or consumer product." (ISOR at 8). This statement is asserted with no substantiation and is simply untrue; the geometric mean is commonly used to estimate the consumption of food products by average users, as noted in more detail in the attached Exponent opinion.

Notably, the CDC, which manages the National Health and Nutrition Examination Survey (NHANES), which is specifically referenced in the same section of the Proposition 65 regulations, has specific guidance recommending the use of the geometric mean instead of the arithmetic mean in cases where the distribution of the data is skewed:

> "Question 6. When should you use geometric means instead of arithmetic means?
>
> Answer: In instances where the data are highly skewed, geometric means should be used. A geometric mean, unlike the arithmetic mean, minimizes the effect of very high or low values, which could bias the mean if a straight average (arithmetic mean) were calculated."[2]

Moreover, the CDC notes that "many continuous variables, like food intakes, are by their nature very skewed."[3] Throughout its guidelines, the CDC highlights the importance of considering the shapes of the distribution of values and applying appropriate statistical methods. It makes no sense for OEHHA to prohibit geometric mean calculations of the "rate of intake or exposure" using NHANES data when the lead agency maintaining the NHANES data specifically endorses the use of the geometric mean when appropriate.

Although the California Chamber and others noted the CDC guidance to OEHHA in the November 2015 comment letter regarding the draft of this proposal, OEHHA fails to address or describe the CDC guidance in its Initial Statement of Reasons. Failing to address this key piece of evidence previously presented to OEHHA leaves the Food Coalition with the impression that OEHHA is not interested in a true dialogue about what is scientifically appropriate and proper and is quite concerning.

It is the data – not a categorical rule – that appropriately determines whether the arithmetic mean, geometric mean, or another measure best represents the average. In turn, the data must be analyzed using standard statistical methodology. For example, if a distribution of data follows the standard bell-shaped curve of a normal distribution, the arithmetic mean would typically be the statistically appropriate estimate of the average. In comparison, if the distribution of the data is skewed (*i.e.*, not bell-shaped), the arithmetic mean will be more influenced by the highest (or lowest) statistical values on the distribution curve and becomes less representative of the "average" value.

Thus, the Mandated Calculation Proposal– in prohibiting the use of measures other than the arithmetic mean – is out of step with the specific guidance relevant to the data that section 25821(c)(2) says should be used.

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[2] http://www.cdc.gov/nchs/tutorials/nhanes/faqs.htm
[3] http://www.cdc.gov/nchs/data/nhanes/nhanes3/inh3qui.pdf

D. The Proposal Will Lead to Overwarning

As OEHHA correctly notes, "For food intake rates, the distribution is most often skewed to the right as discussed in OEHHA, 2012, Chapters 7 and 9. In right-skewed intake distributions, relatively smaller numbers of people consume the product at higher amounts than other consumers of that product." (ISOR at pp. 6-7). For such distribution curves, the arithmetic mean will always be higher than the geometric mean. How much higher will depend on the shape of the distribution curve for all relevant variables. For some food products, the arithmetic mean of exposure can be at the 65th to 80th percentile, as compared to the geometric mean, which is expected to be similar to the median or 50th percentile. In other words, under this scenario, 65 to 80 percent of the population may have exposures below the arithmetic mean.

When businesses elect to provide Proposition 65 warnings for a product, a warning is provided to all users of the product, and not just those who use a product above a certain rate. Of course, providing a warning only to those who use the product above a certain rate is an impossible exercise. Using the geometric mean for products with skewed exposure distributions (such as most food products) leads to warnings for all users when approximately 50 percent of users are above the threshold for exposure. This amounts to over warning for the other half of users whose exposure is below the threshold. But, using the arithmetic mean for such products would lead to warnings for all users when only 20 to 35 percent of users, for example, are above the threshold level, effectively over-warning 65 to 80 percent of users. The result is bad policy, and it is unjustified from both a scientific and public health standpoint.

III. The Proposed Revision to Mandate Facility-Based and Producer-Based Calculation of the Average Concentration Under Proposition 65 Would Impose Tremendous Costs, Is Not Workable, and Is Grossly Inequitable

OEHHA's Proposal to mandate that the "level in question" for food products be based on analytical results specific to a particular food producer or food manufacturer would either grossly increase food costs or food warnings in California, or both. This proposed change should not be adopted.

First, food "producers" could be interpreted to mean farmers with a particular plot of land. There are hundreds of thousands, if not millions, of farmers with particular plots of land all over the world that contribute food ingredients to the California food supply. Testing for Proposition 65 ingredients producer-by-producer would be prohibitively expensive, increasing Proposition 65 compliance costs by over $50 million dollars per year. Just testing for the various chemicals that have been the subject of Proposition 65 notices to date would cost approximately $1,000 per sample and the number of samples required for the entire industry would increase compliance costs dramatically, well over $50 million per year.

Even forcing averaging at the level of a food manufacturing facility would be prohibitively expensive. It is beyond dispute that forcing the collection of facility-by-facility data would

increase costs for all companies with more than one manufacturing facility that might send product to California because all system-wide testing programs would need to be redesigned to be facility-by-facility programs. There are over 250,000 food facilities registered with the U.S. Food and Drug Administration. (See https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm236512.htm). Based on the size of the California economy, the Food Coalition estimates that at least 75,000 of these facilities send foods to California. Requiring each facility to have separate testing based on multiple samples could impact approximately half, or 37,500 facilities. Since testing for the chemicals that have been the subject of Proposition 65 notices targeting food products costs approximately $1,000 per sample. Three extra samples per year at each of 37,500 facilities would result in an additional cost of $112,500,000 per year. The exceptional cost of this proposal has been further confirmed by an informal poll of selected food companies, which have reported expected additional testing costs of up to $750,000 per company.

Second, the Proposal likely will obligate manufacturers to enhance source identity tracing beyond what is currently practical or economically feasible. Fruits from different producers are combined by cooperatives, including significant cooperatives in California. Grains from different producers are combined in various grain storage facilities, and so on.

Third, if OEHHA believes that Proposition 65 issues should be analyzed facility-by-facility for foods, or producer-by-producer, then Proposition 65 Notices of Violation sent by private parties also should be limited to the facility and food producer for which the plaintiff has credible evidence of an exposure above the relevant safe harbor. It would be grossly unfair and completely illogical for OEHHA to move forward with this proposal to amend Section 25821(a) without a concurrent proposal to amend Section 25903 of the Proposition 65 regulations to require the noticing party to identify the food product codes on the container and to limit the notice to the manufacturing facility where the final food product was made. Although the Food Coalition disputes the need for OEHHA's Proposal, the logic of the proposal applies equally to notice letters and the scope of actions they would authorize as it does to the defense of a product covered by Section 25821.

Fourth, while OEHHA asserts that the manner in which the *Beech-Nut* Court applied Section 25821(a) was incorrect, OEHHA does not explain why. If OEHHA is correcting a scientific error that it believes was made by a Court, it should identify the error more specifically and explain the scientific basis for its disagreement.

IV. The Proposal Will Have a Significant Adverse Economic Impact on Business

OEHHA's ISOR in support of the Proposal states incorrectly that it will have no significant adverse impact on business:

> "The proposed regulatory action will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to

> compete with businesses in other states because the proposed amendments to the regulation do not impose any new requirements upon private persons or businesses beyond those that are already required by Proposition 65." (ISOR at 12).

The Food Coalition strongly disputes this assertion. First, the Mandated Calculation Proposal imposes a new requirement on business that is not already required by Proposition 65. The existing statute and regulations do not require the use of the arithmetic mean as the only method for calculating the average intake rate or exposure "regardless of the shape of the distribution that best describes the sampling data." As discussed in above, this is a completely new requirement, not a clarification of an existing requirement.

Second, likely impact of using the arithmetic mean without regard to the distribution of the exposure data is an increase in the number of Proposition 65 warnings on products and the number of consumers who are unnecessarily receiving Proposition 65 warnings. The Proposal purports to "help" businesses by making sure all businesses use the arithmetic mean for food products, even though the data for most foods are skewed. This will force businesses to place warnings on food products that would not have needed a warning in the past because it is scientifically more appropriate to use the geometric mean or some other measure of central tendency in calculating exposure. There also will be a significant cost to re-doing existing product compliance assessments pursuant to this new mandate.

V. There Is a Reasonable Alternative to the Proposal that Would Lessen the Adverse Impacts on Small Business

According to the ISOR, "The proposed regulatory action will not adversely impact small business because it is simply a clarification of the intent of the existing regulations. … OEHHA has determined that there is no reasonable alternative considered by OEHHA, or that has otherwise been identified and brought to the attention of OEHHA, including alternatives that would lessen any adverse impact on small business or would be as effective and less burdensome on small business." (ISOR at 11). As noted earlier, this is a new regulatory requirement, not a clarification of an existing requirement.

This new regulation will have a significant adverse economic impact on businesses, large and small.

There is a reasonable alternative to the Proposal that would lessen any adverse impact on small business: leave the existing regulations in place as they are. This alternative was brought to the attention of OEHHA in a letter from the California Chamber of Commerce dated November 17, 2015. A one-size-fits-all regulation that requires the use of the arithmetic mean even when the distribution of consumption of food products is skewed is not appropriate or helpful. It is bad policy and contradicts sound scientific principles to require the use of the arithmetic mean in every situation "regardless of the shape of the distribution that best describes the sampling data." (ISOR at 7).

VI. Conclusion

For the reasons noted above, the Food Coalition urges OEHHA to withdraw its October 2018 Proposal to amend Section 25821 of the Proposition 65 regulations.

American Beverage Association

By:_____
Maia M. Jack, Ph.D.
Vice President,
Science and Regulatory Affairs

California League of Food Producers

By:_____
Trudi E. Hughes
Director, Government Affairs

Grocery Manufacturers Association

By:_____

Agricultural Council of California

By:_____
Emily Rooney
President

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